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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,198	08/10/2001	James Arthur Hoffmann	X12383N	6700

7590 03/06/2002
Eli Lilly and Company
Lilly Corporate Center
Patent Division DC: 1104
Indianapolis, IN 46285

EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 03/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/928,198

Applicant(s)

HOFFMANN ET AL

Examiner

Regina M. DeBerry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 92-103 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 92-103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendment filed 10 August 2001 (Paper No. 4 and Paper No. 5) has been entered in full. Claims 1-91 were cancelled. New claims 141-152 (renumbered as 92-103 under Rule 1.126) have been entered. Claims 92-103 are under examination. The information disclosure statement filed 10 August 2001 was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Objection to Specification

The disclosure is objected to because of the following informalities: There are two Example 9 (page 58 and 65) in the specification. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 92-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Meere *et al.* (US Patent No. 5,384,132) in view of Buch-Rasmussen *et al.* (US Patent No. 5,945,187) and Bornstein *et al.* (US Patent No. 5,681,822).

De Meere teaches pharmaceutical gonadotropin compositions (follicle stimulating hormone) (column 1, lines 1-3, lines 38-43 and lines 57-65). De Meere teaches recombinant human follicle stimulating hormone (FSH)(column 2, lines 24-68; column 6, lines 20-68 and claims). De Meere teaches concentrations of FSH (column 3, lines 1-20). De Meere teaches FSH concentrations that overlap with the concentrations claimed in the instant application. De Meere does not teach concentrations of benzyl alcohol in an aqueous diluent.

Buch-Rasmussen teaches that aqueous solutions or suspensions of medicaments, such as insulin or growth hormones are normally provided with a preservative such as benzyl alcohol. Buch-Rasmussen teaches that benzyl alcohol is approved in small amounts for use in parenteral medicaments (column 1, lines 24-45).

Bornstein teaches that benzyl alcohol is known as a preservative in pharmaceutical formulations based on its antibacterial action and as a solubilizing agent for certain pharmaceutical compounds (column 2, lines 18-24). Bornstein teaches concentrations of benzyl alcohol. Bornstein teaches benzyl alcohol concentrations that

overlap with the concentrations claimed in the instant application (column 2, lines 18-24, Table 1 and Table 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of various concentrations of recombinant human follicle stimulating hormone (FSH) taught by De Meere by using the teachings of benzyl alcohol regarding preserving, concentration and solubilizations taught by Buch-Rasmussen and Bornstein. The motivation and expected success is provided both by Buch-Rasmussen and Bornstein who teach longer storage of pharmaceutical compositions and antibacterial action using benzyl alcohol.

Claims 96-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Meere *et al.* (US Patent No. 5,384,132) in view of Buch-Rasmussen *et al.* (US Patent No. 5,945,187) and Bornstein *et al.* (US Patent No. 5,681,822) as applied to claims 92-95 above, and further in view of Carey *et al.* (US Patent No. 4,746,508). The teachings of De Meere *et al.*, Buch-Rasmussen *et al.* and Bornstein *et al.* are discussed above. None of the references disclose the use of sodium phosphate. Carey *et al.* teach the administration of follicle stimulating hormone and the use of sodium phosphate as a physiologically acceptable carrier (abstract, column 9, lines 8-18 and claims 38, 47 and 64).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of De Meere *et al.*, Buch-Rasmussen *et al.* and Bornstein *et al.* cited above and use the teachings of Carey

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et al. The motivation and expected success is provided by the use of sodium phosphate, which is taught as a physiologically acceptable carrier and offers buffering capacity that maintains the pH.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RMD

RMD
February 26, 2002

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER